In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 13-700V
(to be published)

ZELMA TAYLOR, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Corcoran Filed: March 9, 2018 Decision; Influenza ("Flu") Vaccine; Acute Disseminated Encephalomyelitis ("ADEM"); Multiple Sclerosis ("MS"); Onset

Mark T. Sadaka, Mark T. Sadaka, LLC, Englewood, NJ, for Petitioner.

Jennifer L. Reynaud, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On September 19, 2013, Zelma Taylor filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program")[2], alleging that she experienced acute disseminated encephalomyelitis ("ADEM") due to her receipt of an influenza ("flu") vaccine on September 29, 2010. Petition ("Pet.") (ECF No. 1) at 1, 5. An entitlement hearing was held in this matter on April 17, 2017, and May 25-26, 2017. After considering the record as a whole, I find that Petitioner has failed to carry her burden establishing her non-Table claim, and

[1] This Decision will be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Decision in its present form will be available. *Id.*

[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. § 300aa-10 through 34 (2012)). References to the statute herein shall omit the statutory prefix.

therefore has not demonstrated entitlement to compensation under the Vaccine Program. Even though Petitioner's illness most likely post-dated her vaccination, the overall timeframe in which her neurologic symptoms began and progressed is inconsistent with having been caused by the flu vaccine.

I. Factual Background

The record in this case consists of Ms. Taylor's medical records, the testimony of multiple experts and two fact witnesses, and medical or scientific literature submitted by the parties in support of their respective positions. I have reviewed the entire record as required by the Vaccine Act.

Pre-Vaccination Medical History

Before receipt of the vaccine at issue, Ms. Taylor was relatively healthy, with no significant issues relevant herein – with the exception of emergency treatment she received about six months before the vaccination. On March 4, 2010, Petitioner reported to the emergency room at the University of Mississippi Medical Center with complaints of eye pain, double vision, distorted peripheral vision, and headaches that had been ongoing for three weeks. Ex. 8 at 1336. The intake physician proposed, after an initial examination, that Petitioner might be suffering from cranial nerve VI palsy. *Id.* at 1337, 1345. On March 17, 2010, Petitioner presented to Dr. Kimberly Crowder at the McBryde Eye Clinic in Jackson, Mississippi for an appointment concerning her eye pain, blurred vision, and headaches. *Id.* at 1355. Dr. Crowder diagnosed Petitioner with migraine headaches and right cranial nerve VI palsy, and prescribed Nadolol. *Id.* at 1356. Dr. Crowder directed Petitioner to schedule a follow-up appointment for a glaucoma test. *Id.* No MRI was performed at that time.

Petitioner returned to the emergency room two times thereafter in the next several months. On March 23, 2010, she presented with complaints of cough and congestion. Ex. 8 at 1357-58. The treating physician diagnosed Petitioner with an upper respiratory infection, and directed her to "drink lots of fluid" and use medication as needed. *Id.* at 1365. Petitioner returned to the emergency room several months later, on July 8, 2010, with complaints of an earache, fever, and chills, starting three day earlier. *Id.* at 1368. She was diagnosed with pharyngitis and prescribed antibiotics. *Id.* at 1374.

Besides the above, Ms. Taylor had several more routine medical appointments prior to the vaccination in question. On June 22, 2010, for example, Petitioner (who was then eighteen years old) presented to the Hinds County Health Department for a routine health exam prior to entering college. Ex. 1 at 9. She was seen by a nurse practitioner, Ms. Joselyn Bacon, who noted that Petitioner was healthy and physically fit to participate in athletics. *Id.* at l1. Additional pre-vaccination records indicate that Petitioner presented to the Wesson Health Center for a rash and a swollen finger on August 31, 2010. Ex. 1 at 6. She was prescribed a steroid cream for the rash,

and directed to take Tylenol as needed for her finger injury. *Id.* A week later, on September 7, 2010, Petitioner presented again to the Wesson Health Center for a sore throat. *Id.* at 5. She was diagnosed with viral pharyngitis. *Id.* She returned on September 9, 2010, with complaints of post-nasal drainage and was prescribed Flonase. *Id.*

Vaccination and Subsequent History

On September 29, 2010, Petitioner received the flu vaccine at the Wesson Health Center on the campus of Millsaps College in Jackson, Mississippi. Ex. 1 at 1. Two weeks later, on October 14, 2010, Petitioner returned to the Wesson Health Center complaining of left ankle pain and swelling resulting from a flag football game injury. Ex. 1 at 4. Petitioner identifies this as the onset of her alleged vaccine injury, averring in her affidavit that she quit flag football on that day because "her balance was less steady," which caused the accident for which she then sought treatment. She also recalled in her affidavit feeling tired and weak, and struggling to remember game plans. *See* Affidavit of Zelma Taylor, filed as Ex. 12 (ECF No. 30-1) at 2. The treating physician at this time specifically noted, however, that although Petitioner did have mild swelling in her ankle, she showed no signs of "neurologic deficit." Ex. 1 at 4. The medical records from this doctor's visit do not otherwise corroborate Ms. Taylor's statements about the cause of this injury.

At the end of the month, on October 27, 2010, Petitioner went back to Wesson Health Center with complaints of "lower back pain radiating to the inguinal area" as well as painful urination. Ex. 1 at 7. The attending treater diagnosed Petitioner with dysuria and prescribed her Pyridium. *Id.* About two weeks later, on November 12, 2010, Petitioner presented to the CarePlus Clinic in Jackson, Mississippi, with complaints of continued headaches, fever, tiredness, fatigue, a pruritic (itchy) rash on her back, and nasal congestion. Ex. 5 at 1211. She was taking Claritin and ibuprofen daily. *Id.* The treating physician prescribed Bactrim (an antibiotic), Celestone (a corticosteroid), and Robitussin for cough, and counseled Petitioner on weight loss. *Id.* at 1212. She was also directed to schedule a follow-up appointment for monitoring of hypertension and allergic rhinitis. *Id*.

Record Evidence of Incipient Neurologic Injury

On December 21, 2010 (nearly three months after the September vaccination), Ms. Taylor returned to the CarePlus Clinic with concerns that she was diabetic because she was experiencing intermittent numbness in her left foot (not her right), but which could be relieved by stomping her foot on the ground. Ex. 5 at 1213.[3] Petitioner did not report at this time precisely when the numbness had begun, although she did not say it had been long-standing. Petitioner's overall assessment included controlled allergic rhinitis and uncontrolled obesity. *Id.* The treating physician prescribed Clarinex, and directed Petitioner to return to the clinic as needed. *Id.* The clinic

[3] Neuropathies often accompany diabetes, and can be characterized by numbness or tingling, muscle weakness, loss of balance or reflexes, generalized pain, weight loss, or increased heart rate, depending on the type of diabetic neuropathy experienced. *See Diabetic Neuropathy*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/diabetic-neuropathy/symptoms-causes/syc-20371580 (last accessed on Feb. 26, 2018).

physician also noted that she explained to Petitioner that obesity was a risk factor for diabetes and breast cancer. *Id.* It does not appear that the treating physician observed or noted any neurological concerns during the visit.

The next month, on January 12, 2011 (now over three months post-vaccination), Petitioner was taken by ambulance to the emergency room at the University of Mississippi Medical Center in Jackson for complaints of vomiting and abdominal pain and cramping. Ex. 7 at 1217-22; Ex. 2 at 496-98. A CT scan revealed evidence of a left ovarian cyst, but normal functioning in the gallbladder and biliary tract. Ex. 2 at 80-81. Ms. Taylor was ultimately diagnosed with gastritis and discharged the same day *Id.* at 493, 503.

Petitioner thereafter sought additional medical treatment at Tharp Family Eye Care on February 3, 2011, complaining of blurred vision, nausea, headaches, and a broken blood vessel in her eye. Ex. 3 at 1175. The ophthalmological evaluation revealed a subconjunctival hemorrhage which her treaters believed would heal without treatment. *Id.* Petitioner also complained of double vision during this visit. *Id.* She was ultimately diagnosed with diplopia and referred to the Jackson Eye Institute. *Id.* at 1173, 1175.

Hospitalization and ADEM Diagnosis

Ten days later, on February 13, 2011 (over four months post-vaccination), Petitioner presented again to the ER at the University of Mississippi Medical Center with complaints of bilateral leg pain, which she reported had begun three to four weeks earlier (meaning no sooner than mid-January), along with double vision. Ex. 2 at 253, 287. Petitioner also reported slurred speech and weight problems. *Id.* at 287. Both a CT scan and MRI performed during the visit indicated that Petitioner's brain showed "extensive abnormal enhancing[4] signal changes throughout the supratentorial white matter," deep gray matter, and brainstem, which suggested an "aggressive demyelinating process" was occurring. *Id.* at 74, 77. Petitioner's cerebral spinal fluid ("CSF") testing also revealed the presence of oligoclonal bands.[5] Ex. 8 at 2758.

Petitioner's treating neurologist, Dr. Mohammad Ullah, initially opined that Petitioner had multiple sclerosis ("MS"), but that same day the diagnosis was changed to acute disseminated encephalomyelitis ("ADEM"). *Id.* at 299, 302-03. The record itself does not explain the rationale for this alteration; it does appear that a neurology resident responsible for Petitioner's immediate care made the first ADEM diagnosis, but it was later verified by another physician, Dr. James

[4] While enhancing lesions can be found in both MS and ADEM patients, lesions revealed by an MRI that are suggestive of ADEM are "multifocal" or "hyperintense" (with FLAIR T2-weighted images) and predominately either resolve or result only in residual deficits over the course of the illness. Enhancing lesions in an MS patient, however, usually reveal the presence of new lesions. L. Krupp et al., *Consensus Definitions Proposed for Pediatric Multiple Sclerosis and Related Disorders*, 68 Neuro. S7, S8-S9 (2007), filed as Ex. D (ECF No. 35-4).

[5] Oligoclonal bands are bands of immunoglobulin. Abnormal patterns of oligoclonal bands have been reported in 70 to 80 percent of patients with MS. *See Oligoclonal Banding, Serum and Spinal Fluid*, Mayo Clinic, https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8017 (last accessed on Feb. 26, 2018).

Corbett. *Id.* at 300, 303, 305. Petitioner was subsequently treated with intravenous steroids and transferred to inpatient rehabilitation on February 18, 2011, where her condition was monitored. Ex. 2 at 114-17. Petitioner was discharged on March 8, 2011, with diagnoses of ADEM, thrombocytosis, hypertension, weakness, and cognitive and balance impairment. *Id.* at 122. Medications prescribed upon discharge included Prozac and Prednisone. *Id.* at 123.

Three weeks after her discharge, Petitioner went back to the ER on March 31, 2011, with complaints of chronic headaches and acute onset vomiting. Ex. 7 at 1238. Following this event, Petitioner had a visit with another neurologist, Dr. David Sinclair, on April 5, 2011. After reviewing her symptoms, Dr. Sinclair opined that Petitioner had experienced a "reasonable recovery" from ADEM, but was still emotionally upset and had developed insomnia. Ex. 2 at 108-09; Ex. 10 at 3062. Office notes taken during this visit also suggested that Ms. Taylor was experiencing problems stemming from a lack of social judgment (reflective of a frontal lobe injury). Ex. 2 at 109. Dr. Sinclair ultimately assessed Petitioner with "post-immunization ADEM [and] residual emotional disinhibition" as well as a "pseudobulbar affect."[6] Ex. 2 at 108; Ex. 10 at 3062. It is not clear from the record how Dr. Sinclair arrived at his "post-immunization" ADEM diagnosis. He noted, however, that Ms. Taylor did "stand a good chance of seeing more cognitive recovery." *Id.* Dr. Sinclair directed Petitioner to return for a follow-up appointment with him in six months. Ex. 2 at 108.

Subsequent Health Problems in 2011

On June 20, 2011, Petitioner was found unresponsive in her home. Ex. 7 at 1253, 1255. EMS personnel noted that Ms. Taylor had become "awake and alert with some confusion" shortly after their arrival. *Id.* Petitioner's mother told EMS personnel that Petitioner had been diagnosed with ADEM in February, which caused her to experience loss of consciousness, vision problems, and seizure-like activities. *Id.* Petitioner had two more seizure-like episodes prior to arriving at the hospital. *Id.* Upon evaluation, Petitioner was diagnosed with a seizure disorder and hypertension. Ex. 8 at 2331, 2343. During a neurological evaluation the following day, treaters opined that Petitioner was suffering from a seizure disorder. *Id.* at 2349. These symptoms spontaneously resolved and Petitioner was discharged, given anti-seizure prescriptions, and directed to follow-up with her neurologist. *Id.* Although ADEM was noted in her health history chart, it does not appear that any treater related the seizures to that prior diagnosis. *Id.* at 2332.

Petitioner thereafter obtained a neurologic evaluation at the University of Mississippi Medical Center on June 26, 2011. Ex. 2 at 93. Besides symptoms consistent with what is described above, Petitioner also complained of frequent falls, acute vision changes, headaches, and staring spells during this visit. *Id.* The attending physician's impression indicated that

[6] A pseudobulbar affect is "a condition characterized by episodes of sudden uncontrollable and inappropriate laughing or crying." *Pseudobulbar Affect*, Mayo Clinic, https://www mayoclinic.org/diseases-conditions/pseudobulbar-affect/symptoms-causes/syc-20353737 (last accessed on Feb. 26, 2018). This type of event usually manifests with patients who have experienced a neurological condition or injury.

Petitioner developed ADEM in February 2011 followed by a seizure disorder. *Id.* at 94. An EEG was performed and findings were consistent with complex partial seizures. *Id.* Petitioner's treater recommended that her Carbamazepine dosage be increased, and directed her to begin taking an additional anti-seizure medication. *Id.*

On July 29, 2011, Petitioner had a follow-up appointment with Dr. Sinclair. Ex. 8 at 2980. Upon examination, Dr. Sinclair opined that to date, Petitioner had continued to experience a labile affect, a spastic catch to the left upper extremity, absent reflexes, and impaired gait, although she was able to ambulate. *Id.* Dr. Sinclair diagnosed Petitioner with a static encephalopathy, partial onset seizures, and a vitamin D deficiency, and prescribed additional medications for her. *Id.* On October 21, 2011, Petitioner again presented to Dr. Sinclair. *Id.* at 2991. An examination indicated impaired gait, but otherwise normal muscle tone, strength, and reflexes. *Id.* Dr. Sinclair's assessment remained the same, but he also noted symptoms related to ataxia and a mild pseudobulbar affect. *Id.* Finally, Dr. Sinclair recommended that Petitioner discontinue her seizure medication, given that she had been seizure-free for five months. *Id*. By November 2011, however, Petitioner's seizures returned, and she was directed to begin taking Keppra. *Id.* at 2998.

Treatment in 2012 and Beyond

Ms. Taylor visited the emergency room six times between January and September 2012. *See* Ex. 2 at 1-5; Ex. 4 at 1178-80; Ex. 7 at 1287-1308. At the July 5, 2012 visit to the ER at the Mississippi Baptist Medical Center, she reported abdominal pain. Ex. 4 at 1188. The attending physician, Dr. Michael McKay, noted that Petitioner was 17 weeks pregnant with twins and had a history of neurological disorder. *Id.* Petitioner reported during this visit that her past "neurologic problems were caused by her flu vaccine." *Id.* Dr. McKay's overall impression included abdominal pain, constipation, and twin pregnancy. *Id.* at 1189. Petitioner was discharged and directed to follow up with her obstetrician. *Id.*

During an additional visit to the ER at the University of Mississippi Medical Center on July 20, 2012, Ms. Taylor reported vaginal bleeding related to pregnancy. Ex. 2 at 13. The attending obstetrician evaluated Petitioner for a suspected miscarriage, but determined none had occurred. Ex. 2 at 13-14. Petitioner was admitted to the hospital again on September 10-12, 2012, with complaints relating to possible contractions. Ex. 16 at 3208. During the hospital stay, Petitioner had two seizures, for which she was treated with IV and Keppra. *Id.* at 3209. Apart from the seizures, Petitioner's fetal monitoring indicated normal function. She was also treated for a urinary tract infection diagnosed upon admission. *Id.* Petitioner was readmitted to the hospital from September 15-16, 2012, with complaints of nausea and vomiting. Ex. 2 at 50. These complaints improved after IV treatment and anti-emetics. *Id.*

Petitioner gave birth to twins on November 3, 2012. Ex. 2 at 64. Upon arrival at the

hospital, it was noted that Ms. Taylor was in complete dilation. *Id.* She was immediately taken to the OR for a cesarean delivery—no complications were noted for the remainder of her stay. *Id.* at 65. She was discharged five days later. *Id.* at 64. Discharge notes suggested that Ms. Taylor was again placed on Keppra for her seizure disorder after consulting with the neurology department upon discharge. *Id.*

On December 11, 2012, Ms. Taylor saw Dr. Robert Herndon for a follow-up appointment for her seizure disorder. Ex. 8 at 2631. Petitioner reported increased seizures during her pregnancy and an increase in her Keppra dosage to counteract the same. *Id.* Dr. Herndon stated that Petitioner complained of drowsiness and fatigue, but noted that her seizures were well controlled. He directed Petitioner to continue Keppra and follow up with an appointment in six months. *Id.* at 2637. Petitioner returned for that appointment on June 11, 2013, seeing Dr. Danett Dillon. *Id.* at 2669. Petitioner presented with complaints of seizures (roughly two per week), depression, and fatigue. *Id.* Dr. Dillon treated Petitioner for on-going seizures and increased her Keppra dosage. *Id.* Dr. Dillon also prescribed Prozac for Petitioner's depression. *Id.* at 2671.

Petitioner's next medical records are dated from December 2013 to November 2014, and primarily detail visits to the Jackson-Hinds Comprehensive Health Center in Jackson, Mississippi. Ex. 11 at 3101. During these visits, Petitioner reported various health concerns, including a urinary tract infection (Ex. 11 at 3105), routine gynecological exam (Ex. 11 at 3115), birth control (Ex. 11 at 3101, 3111, 3113, 3118; Ex. 16 at 4165), upper respiratory infection (Ex. 11 at 3113), postpartum examination (Ex. 11 at 3109), and constipation (Ex. 16 at 4167).

Petitioner returned for a follow-up with Dr. Dillon on July 29, 2014, after having a breakthrough seizure the night before. Ex. 16 at 3807, 3809. Upon a neurological evaluation, Dr. Dillon's assessment notes indicated that Petitioner's partial complex seizures were well-controlled on Keppra, and he directed Petitioner to continue her normal dosage. *Id.* at 3809. Dr. Dillon also indicated that Petitioner had been experiencing hot flashes, likely due to her birth control medication. *Id.* Dr. Dillon recommended that Petitioner continue taking Keppra and return for a follow-up in three months. *Id.* For her on-going depression, Dr. Dillon recommended discontinuing Prozac and starting Lexapro to see if better management results could be obtained. *Id.*

On August 9, 2014, Petitioner saw Dr. Jared Taylor, a psychiatrist, for complaints associated with depression. Ex. 16 at 3819. During this visit, Petitioner specifically stated that she has been depressed since her "allergic reaction in 2010 to the influenza vaccine." *Id.* Petitioner also linked the vaccine to her neurologic condition, stating to Dr. Taylor that her seizure disorder and left side weakness resulted from the vaccine. *Id.* Dr. Taylor's notes also indicate that Petitioner reported trouble falling asleep, decreased energy, an inability to concentrate, and feelings of guilt. *Id.* Dr. Taylor ultimately diagnosed Petitioner with a major depressive disorder and recommended that she continue Lexapro as prescribed by Dr. Dillon. *Id.* at 3822. In addition,

Dr. Taylor prescribed Ambien for sleeping troubles, and directed Petitioner to follow up in four weeks. *Id.*

The remaining medical records submitted detail visits to the University of Mississippi Medical Center from May 2015 to May 2016. Petitioner saw Dr. Dillon on May 19, 2015, for a follow-up appointment concerning her seizure disorder. Ex. 16 at 3905. Dr. Dillon noted that Petitioner was still experiencing seizures, roughly two to three times a month. *Id.* Dr. Taylor recommended that Petitioner continue her treatment course, including taking her normal dosage of Keppra. *Id.* at 3907. The remaining 2015 visits indicate treatment for tremors and other non-neurologic issues. Ex. 16 at 3913, 3918.

The final records submitted detail an emergency room visit on May 9, 2016. Ex. 40 at 4209. Petitioner had experienced a seizure-related fall. *Id.* The attending physician noted Ms. Taylor's medical history included ADEM and a seizure disorder. *Id.* at 4215. An MRI completed during the visit now revealed "white matter lesions throughout the brain" and "aged atrophy." *Id.* at 4214, 4217. More specifically, the MRI revealed "extensive abnormal T2/Flair signal throughout the supratentorial white matter and brainstem [and deep gray matter] . . . ." *Id.* at 4225. The attending physician also noted "extensive enhancement associated with [white matter] lesions" along with "peripheral ring-like enhancement." *Id.* The overall impression was of an "aggressive demyelinating process, with infectious process/encephalitis, atypical vasculitis, [and possible] Lyme disease." *Id.* The MRI also revealed a "slightly complex pineal cyst," which treaters felt merited a follow-up MRI in six months. *Id.* A CT scan of the head and spine was also taken during this visit, but "no acute abnormality" was noted. *Id.* at 4215. Petitioner was discharged on May 13, 2016, with instructions to continue taking Keppra two times daily for thirty days. *Id.* at 4219. While Petitioner's treaters did mention ADEM as part of her health history in the records from this event, it does not appear they designated the results of this subsequent MRI with ADEM or MS, or connected it to her 2011 hospitalization, nor does it appear that treaters changed Petitioner's diagnosis (based on the records submitted). *See id.* at 4225.

II. Fact Witness Testimony

A. *Brenda Taylor*

Brenda Taylor is the Petitioner's mother. Tr. at 297. She testified briefly at hearing about her daughter's overall clinical course.

Mrs. Taylor began by describing Petitioner's condition prior to receiving the vaccine. Before her symptom onset, Petitioner was a bright, intelligent, college student. Tr. at 298. She had received a full scholarship to Millsaps College to study computer science engineering. *Id.* at 299. Mrs. Taylor testified that her daughter was on the honor roll, involved in the local community and participated in school activities, such as band. *Id.* at 298-99. By mid-October 2010, however,

around the time Petitioner injured her ankle during a flag football game, Mrs. Taylor began noticing a change in her daughter's condition. Tr. at 300. She described Petitioner as looking fluid-filled, and noted that she had a drooping eye and complained of left-sided weakness. *Id.* at 306. A few weeks later, in November, Petitioner expressed the desire to withdraw from school, finding it too difficult to keep up given how sick she felt. *Id.* at 302-03.

Mrs. Taylor next recounted her daughter's appointment in December 2010, where she complained of foot numbness, and her emergency room visit in January 2011 for abdominal pain. *Id.* at 307-09. She expressed frustration that treaters could not give her daughter a clear diagnosis, and seemed to somewhat brush her off. Thus, at the January 2011 visit, Petitioner's treaters did little more than declare her to be under increased stress, suggesting she drink more fluids but doing little else to assist her. *Id.* at 310. Mrs. Taylor stated that she would describe her daughter's condition as a "failure to thrive." *Id.* at 311.

Mrs. Taylor acknowledged that the Petitioner did experience some vision problems prior to receiving the flu vaccine, but maintained that the blurred vision or double vision continued into mid-November 2010, resolving not long thereafter. Tr. at 313, 342. However, she later stated that her daughter experienced blindness during her February 2011 emergency room visit. *Id.* at 314. By 2011, her daughter's condition tended to worsen, and now included symptoms such as leg pain, weakness, and altered behavior ("talking out of her head" and "blurting out"). *Id.* at 315-17. Mrs. Taylor also noted that her daughter began to have seizures in June 2011 and began to lose the ability to walk or control her hands. *Id.* at 323, 325.

As of 2016, Mrs. Taylor stated, Petitioner requires constant care and is confined to a wheelchair. Tr. at 334. While she attends rehab regularly, she cannot drive and continues to experience stability problems. *Id.* at 334-35. She requires assistance with meals, laundry, and general personal health activities. *Id.* at 336. She is also unable to care for her children, and depends on help from family, friends, and home health-care providers every day. *Id.*

B. *Zelma Taylor*

Petitioner also testified at hearing. Tr. at 342-48. Her testimony largely consisted of her own recollections of her overall health history prior to receiving the flu vaccine, as well as attempting to describe the symptoms that followed. Although Petitioner characterized her memory as somewhat "foggy" at times, she stated that she began experiencing symptoms, including double vision, after receiving the flu vaccine. Tr. at 343. Petitioner noted that she remembers withdrawing from college because she felt she was having trouble concentrating and found it difficult to keep up with her coursework. *Id.* at 344. Petitioner stated that she did not have these problems when she was in high school. *Id.* at 345. In addition, Petitioner testified that she now requires assistance with most daily activities. Tr. at 346. She can no longer care for her

children, and she continues to experience seizures every other day. *Id*. at 347.

III. Expert Testimony

A. Dr. Lawrence Steinman

Dr. Steinman provided an opinion on Petitioner's behalf as to the etiology of Ms. Taylor's condition, along with the flu vaccine's purported causal role. Dr. Steinman opined that Ms. Taylor was correctly diagnosed with ADEM, and that her illness was vaccine-caused, but added that even if the proper diagnosis were MS, and/or that her MS predated the vaccination, his opinion of the causal role played by the flu vaccine (whether directly or by significant aggravation) would remain the same. Tr. at 12-13. Dr. Steinman filed a single expert report. *See* Steinman Report, dated Dec. 15, 2015, filed as Ex. 15 (ECF No. 40-2) ("Steinman Rep.").

Dr. Steinman obtained his medical degree from Harvard Medical School, where he completed an NIH fellowship in chemical neurobiology. Tr. at 5; Steinman CV, filed as Ex. 14 (ECF No. 40-1) at 1. After medical school, Dr. Steinman went on to complete both a pediatrics and neurology residency at Stanford University. Tr. at 6; Steinman CV at 1. He then joined the faculty at Stanford in 1980, where he presently serves as the George A. Zimmerman Professor of Neurological Sciences, Neurology, Genetics and Pediatrics. *Id.* During his tenure, Dr. Steinman estimated that he has treated over 2,500 patients with either MS, GBS, or ADEM. Tr. at 7. Dr. Steinman has also published extensively in peer-reviewed journals on topics including neuroimmunology and MS. *Id.* He is an exceedingly qualified expert on the subjects at issue in this case, and has testified numerous times in the Vaccine Program.

To begin, Dr. Steinman reviewed Ms. Taylor's symptoms and the progression of her condition compared to the most common features of ADEM. Dr. Steinman categorized ADEM as an acute infiltration of immune system lymphocytes into the brain, manifesting with symptoms such as blindness, blurred vision, or vomiting, depending on which part of the brain is affected. Tr. at 25-26. ADEM and an acute attack of MS "look very much the same," given that the underlying immunological pathology is the same or similar. *Id*. Because the two diseases are "very closely related," he did not find it of particular importance in this case to distinguish between the two, although he expressly stated that he felt the ADEM diagnosis was correct. *Id.* at 12, 24.

Dr. Steinman discussed Ms. Taylor's medical history prior to her flu vaccination and its relationship to her eventual diagnosis. Tr. at 13-14. He acknowledged that Ms. Taylor's March 2010 diagnosis of cranial nerve palsy was a "major neurological finding." *Id.* at 13. Unlike Respondent's expert (Dr. Sriram), however, Dr. Steinman opined that Ms. Taylor's symptoms at this time, including double vision and headaches, were attributable to migraines rather than

evidence of some pre-vaccination neurologic symptoms related to her later ADEM-like presentation in 2011. *Id.* at 13-14, 44, 61; Steinman Rep. at 1-2. In so stating, he emphasized the trust he placed in the original determination made by Petitioner's treaters that she had ADEM. Tr. at 14.

According to Dr. Steinman, the flu vaccine triggered Ms. Taylor's ADEM via the biologic process of molecular mimicry. Steinman Rep. at 1. His testimony on this point revolved around a concept that has been largely accepted in the medical community (and often in the Vaccine Program as well): that antibodies produced to fight off a foreign infectious antigen (or generated in response to a vaccine) can mistakenly attack, or cross-react with, myelin basic protein ("MBP") (a primary protein component of human nerves), causing damage to the nerve's myelin sheath and resulting in disease. *Id.* at 1, 8-14; *see also* L. Steinman, *Autoimmune Disease*, Scientific American 107 (1993), filed as Ex. 29 (ECF No. 72-3); K. Wucherpfennig et al., *Recognition of the Myelin Basic Protein Peptide by Autoantibodies and HLA-DR2 Restricted T Cell Clones from Multiple Sclerosis Patients: Identity of Key Contact Residues in the B-cell and T-cell Epitopes*, 100 J. Clin. Investigation 1114 (1997), filed as Ex. 30 (ECF No. 72-4) (case study concluding that the flu virus components share molecular similarities with the MPB - specifically the "HFFK" amino acid sequence); Steinman Rep. at 15.

To establish the scientific basis for this theory with respect to the flu vaccine, Dr. Steinman proposed a cross-reaction between components in the 2010-2011 flu vaccine and the MBP via one of two central nervous system ("CNS") proteins, MOG and CNPase.[7] Steinman Rep. at 9, 11; Tr. at 35; S. Markovic-Plese, et al., *High Level of Cross-Reactivity in Influenza Virus Hemagglutinin-Specific CD4+ T-cell Response: Implications for the Initiation of Autoimmune Response in Multiple Sclerosis*, 169 J. Neuroimmunology 31-38 (2005), filed as Ex. 24 (ECF No. 71-8) ("Markovic-Plese"). Markovic-Plese was a case report study of a single MS patient, in which increased cross-reactivity involving the Influenza A vaccine was observed. The paper studied both MOG- and CNPase-derived peptides, and confirmed the "high stimulatory potency" of two MOG- and one CNPase-derived peptides as antigens capable of inducing cross-reactivity responses. Markovic-Please at 37. Dr. Steinman opined that the vaccine Petitioner received also contained an influenza hemagglutinin protein that could similarly have cross-reacted with the proposed self antigens. Steinman Rep. at 12; Tr. at 32.

In reaction to Respondent's challenge to the Markovic-Plese paper as not supporting the contention that CNPase proteins share enough sequential homology with the flu vaccine

[7] Myelin Oligodendrocyte Glycoprotein or "MOG," is a membrane protein located on the oligodendrocyte cell surface of the myelin sheath. Due to its location, it is considered a primary target antigen involved in immune-mediated demyelination. *See MOG*, Nat'l Inst. Health, https://www.ncbi nlm nih.gov/gene/4340 (last accessed on Feb. 26, 2018). CNPase (or "2',3'-Cyclic-nucleotide 3'-Phospohodiesterase") is a myelin-associated enzyme encoded by the CNP gene. *See CNP*, Nat'l Inst. Health, https://www ncbi nlm nih.gov/gene/12799#general-gene-info (last accessed Feb. 26, 2018).

administered to Ms. Taylor for molecular mimicry to occur, Dr. Steinman maintained that exact sequence homology was not needed to initiate an adverse reaction based on molecular mimicry, as long as *structural* homology, based on protein three-dimensional tertiary structure, exists. *Id.* at 35, 38. Dr. Steinman acknowledged that the CNPase sequence studied in the Markovic-Plese paper does not in fact display a protein sequence *fully* identical to anything in the flu vaccine to a twelve amino acid sequence, but he maintained that the sequence studied in the Markovic-Plese paper nevertheless could prompt an immunologic response as long as homology extended to a five amino acid sequence. *Id.* at 35.

Alternatively, Dr. Steinman opined that the cross-reaction instigated by components of the flu vaccine could occur via an autoimmune attack on ganglioside molecules in the CNS. Steinman Rep. at 9; Tr. at 31, 39, 54; I. Nachamkin, et al., *Anti-Ganglioside Antibody Induction by Swine (A/NJ/1976/H1N1) and Other Influenza Vaccines: Insights into the Vaccine-Associated Guillain-Barré Syndrome*, 198 J. Infectious Disease 226-33 (2008), filed as Ex. 27 (ECF No. 72-1) ("Nachamkin"); *see also* D. Wang, et al., *Uncovering Cryptic Glycan Markers in Multiple Sclerosis (MS) and Experimental Autoimmune Encephalomyelitis (EAE)*, 75 Drug. Dev. Res. 172-88 (2014), filed as Ex. 28 (ECF No. 72-2) (study finding that anti-glycan antibodies are detectable in the spinal fluid of MS patients). As Dr. Steinman explained, the flu virus enters the host cell by binding to the sialic acid receptor on the cell surface, and once released, the bound virus mimics a GM1 epitope, resulting in neuro-inflammation. Steinman Rep. at 13-14. In Nachamkin, researchers determined that the H1N1 vaccine had induced the production of anti-ganglioside antibodies in mice, further supporting their overall conclusion that the H1N1 vaccine can induce a peripheral neuropathy, Guillain-Barré syndrome, in this manner. Nachamkin at 226-27. Because the version of the flu vaccine at issue in this case also includes an H1N1 component, Dr. Steinman proposed that the Nachamkin paper supports the contention that the flu vaccine Petitioner received could have the same effect. *Id.* at 13.

As to onset, Dr. Steinman maintained that the autoimmune process instigated by Ms. Taylor's receipt of the flu vaccine resulted in adverse symptoms, including unsteadiness and loss of balance, beginning in October 2010, around the time of her flag football injury, or approximately two weeks after vaccination. Tr. at 41, 43; Steinman Rep. at 25. Alternatively, an onset in November 2010 (when Petitioner sought treatment for headaches and fatigue) would also be medically appropriate. Tr. at 43. However, Dr. Steinman acknowledged that Dr. Sriram's interval, placing onset at 60 days post-vaccination (or in December 2010), would be outside a medically acceptable timeframe. *Id.* at 41-42 ("If it's at the 60 days, as my friend and colleague, Dr. Sriram, says, then it's going to be outside Schonberger and there we have it.").

Even so, Dr. Steinman admitted that he "had to work hardest" to convince himself that *any* of Ms. Taylor's symptoms occurred within a medically reasonable timeframe. Tr. at 41. This in part was due to the inexact "yardstick" that he relied upon to establish the proper timeframe for

onset of vaccine-induced ADEM. Dr. Steinman based his onset determination on two studies in particular – neither of which involved ADEM or CNS neuropathies. Steinman Rep. at 25; L. Schonberger, et al., *Guillain-Barré Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977*, 100 Am. J. Epidemiology 105 (1979), filed as Ex. 35 (ECF No. 72-9) (allowing for a 5-10 week onset for GBS following the flu vaccine) ("Schonberger"); A. Langmuir, et al., *An Epidemiological and Clinical Evaluation of Guillain-Barre Syndrome Reported in Association with the Administration of the Swine Influenza Vaccine*, 119 Am. J. Epidemiology 841 (1984), field as Ex. 36 (ECF No. 73-1) ("Langmuir") (allowing for 6-8 week onset of GBS following the flu vaccine). Both Schonberger and Langmuir also involved a different vaccine (the swine flu vaccine), and therefore neither provided a precisely on-point framework for determining onset in this case. Tr. at 42-43. Nevertheless, because each allowed for onset of a demyelinating autoimmune disease to occur from as long as eight (Langmuir) to ten (Schonberger) weeks after vaccination, Petitioner's comparatively shorter onset was in Dr. Steinman's estimation medically reasonable. Steinman Rep. at 26.[8]

In discussing the timeframe for Ms. Taylor's onset, Dr. Steinman noted how Dr. Sriram's counterview (as discussed in greater detail below) about Petitioner actually having experienced a relapsing form of MS predating the September 2010 vaccination played into the timing discussion. Tr. at 42; Steinman Rep. at 1. If, he reasoned, Dr. Sriram were correct generally as well as specifically with respect to her first clear relapse (which Dr. Sriram proposed occurred in December 2010), then the timeframe at issue would be well beyond even what Dr. Steinman (borrowing from the Langmuir and Schonberger articles on GBS) proposed was applicable herein. Tr. at 41. Nevertheless, Dr. Steinman reiterated his opinion that an MS diagnosis was never embraced by Petitioner's treaters, diagnostically or in the treatments they used. *Id.* at 43.

Dr. Steinman also discussed the medical concept of "encephalopathy" – a clinical factor highly associated with ADEM, and therefore relevant in determining the timing of Petitioner's onset of symptoms. Tr. at 14. Dr. Steinman defined an encephalopathy as a context-dependent "altered mental status." *Id.* at 14-15. In analyzing Ms. Taylor's health history, Dr. Steinman

[8] For an alternative measure of what would be a medically reasonable timeframe for development of an autoimmune illness after receipt of the flu vaccine, Dr. Steinman also referenced studies involving the link between the vaccine Pandemrix (an adjuvanted H1N1 flu vaccine never administered in the U.S.) and narcolepsy, which observed evidence of a reaction within eight to ten *months* of vaccination. Tr. at 42; Steinman Rep. at 25; M. Partinen, et al., *Increased Incidence and Clinical Picture of Childhood Narcolepsy following the 2009 H1N1 Pandemic Vaccination Campaign in Finland*, 7 PlosOne e33723 (2012), filed as Ex. 37 (ECF No. 73-2) (case study of 335 narcolepsy patients in Finland in 2002-2009, finding a 17-fold increase in narcolepsy following the Pandemrix vaccine with onset occurring at most eight months post-vaccination); A. Winstone et al., *Clinical Features of Narcolepsy in Children Vaccinated with AS03 Ajuvanted Pandemic A/H1n1 2009 Influenza Vaccine in England*, 56 Dev. Med. Child Neurol. 1117 (2014), filed as Ex. 38 (ECF No. 73-3) (case study of 11 patients in England who developed narcolepsy following the Pandemrix vaccine, finding onset occurred between 3-14 months). But he admitted that the analytical utility of this comparison was limited, since the cited Pandemrix-oriented literature clearly involved a different form of the flu vaccine and disease. Tr. at 42. I also find the analogy to the connection between the flu vaccine and narcolepsy in this case to be inapt because of the difference between the illnesses, and the mechanisms by which they are suspected to occur.

identified multiple instances of possible neurological deficits that could constitute encephalopathic injuries, and therefore corroborated the ADEM diagnosis (as well as the injury's relationship to Petitioner's vaccination). For example, Dr. Steinman opined, Ms. Taylor might have experienced an encephalopathy around the time of her self-described episode of weakness, fatigue, and confusion during her flag football game. Tr. at 20. The headaches and sleepiness complained of at Petitioner's doctor's visit in November 2010 could also have been the manifestation an encephalopathy. *Id.* at 21. Ms. Taylor's hospitalization on January 12, 2011, for vomiting and abdominal pain, however, was as likely attributable to a gastrointestinal cause as encephalopathic reaction. *Id.* at 21-22. Dr. Steinman was more confident in proposing that Ms. Taylor's hospitalizations on January 13, 2011, and January 20, 2011, were evidence of encephalopathy, given the additional symptoms she reported (blurred vision and language difficulty). *Id.* at 22-23.

Dr. Steinman otherwise acknowledged in his expert report that there is no epidemiologic evidence establishing an association between the 2010-2011 flu vaccine (what Petitioner would have received) and either ADEM or MS. Steinman Rep. at 9.

B. Dr. Nizar Souayah

Dr. Souayah offered one expert report in support of Petitioner's claim (although he did not testify at hearing). *See* Expert Report, dated Apr. 4, 2015, filed as Ex. 13 (ECF No. 33-1) ("Souayah Rep.").[9]

Dr. Souayah is currently a professor of neurology at Rutgers-New Jersey Medical School. Souayah Rep. at 1. He is board certified in neurology and neuromuscular medicine. *Id.* In his practice, Dr. Souayah diagnoses and treats patients with neurological conditions, including ADEM. He is also involved in research investigating the causal relationship between vaccines and neurological adverse reactions. *Id.* Dr. Souayah is licensed to practice medicine in the State of New Jersey. *Id.*[10]

Dr. Souayah's opinion largely mirrored Dr. Steinman's, although Dr. Souayah's report delved further into the debate regarding the proper diagnosis for Ms. Taylor's symptoms. Dr. Souayah began by discussing the accepted clinical criteria for ADEM set forth in the "Brighton Working Group's" levels of diagnostic certainty. Souayah Rep. at 7. He attempted to differentiate

[9] Although Dr. Souayah's expert report references various items of medical literature in support of his opinions in this case, Petitioner did not file any of the items of literature referenced, and they are therefore not discussed (except when an identified article was also filed by Respondent).

[10] Because Petitioner did not file a CV setting forth Dr. Souayah's qualifications and background, I can only draw from representations about those matters set forth in the report itself.

the criteria associated with ADEM from those relevant to MS, acknowledging that this was not easy to do. *Id.* at 10. To do so, Dr. Souayah referenced a study also cited by Respondent, which focused on the differences in criteria of both illnesses. *Id.*; *see also* L. Krupp, et al., *Consensus Definitions Proposed for Pediatric Multiple Sclerosis and Related Disorder*s, 68 Neurology S7-12 (2007), filed as Ex. D (ECF No. 35-4) ("Krupp"). Dr. Souayah stated that ADEM onset is understood to be polysymptomatic, and accompanied by an encephalopathy - defined by an altered state of consciousness, behavior, or cognition. Souayah Rep. at 10. Evolution of symptoms over a period between one week to three months, with subsequent improvement or recovery, is typical of ADEM. *Id.* However (and similar to Dr. Steinman), Dr. Souayah disagreed with Krupp's conclusion that an encephalopathy is a *prerequisite* for an ADEM diagnosis. *Id.*

Dr. Souayah also discussed the diagnostic criteria for the recurrent form of ADEM, noting that interpretation of a post-ADEM symptom as evidence of disease relapse was "more contentious." Souayah Rep. at 13. In his view, recurrent ADEM is characterized by the reoccurrence of symptoms within three months following original onset, and is only properly diagnosed if the new symptoms are reflective of the initial onset symptoms. *Id.* In addition, he opined, new lesions and resolution of older lesions should also occur. *Id.* However, if the course of symptomology does not present in a polysymptomatic manner, or new lesions occur outside of the relapse timeframe, or a third event occurs, an MS diagnosis is likely more accurate. *Id.*

Based on his review of what he deemed the correct clinical criteria, Dr. Souayah opined that Ms. Taylor had been correctly diagnosed with ADEM in February 2011 based on diagnostic level one (characterized by the demonstration of diffuse or multifocal areas of demyelination, or focal or multifocal findings affecting the CNS, such as an encephalopathy or cranial nerve abnormalities). Souayah Rep. at 8-9. But Ms. Taylor's earlier symptoms (occurring from October 2010-February 2011, and including memory loss, unsteady gait, loss of vision, slurred speech, and demonstrated demyelination) fulfilled the level one criteria for ADEM as well. *Id.* at 9. Thus, in his view Petitioner's onset began two weeks after vaccination, manifesting as unsteady gait, then worsening over the ensuing 14 weeks, based on the record evidence of treatment she received from November 2010 until February 2011. Souayah Rep. at 15. While Dr. Souayah noted other possible diagnoses included monophasic ADEM, relapsing ADEM, and relapsing-remitting MS, he opined that Ms. Taylor's symptomology course was most consistent with monophasic ADEM. *Id.*

Dr. Souayah dismissed Dr. Sriram's counterview that Ms. Taylor had pre-existing MS at the time of her vaccination, opining that her diagnosis of cranial nerve palsy in March 2010 was an isolated event unrelated to her subsequent course of symptoms. Souayah Rep. at 9. In his view, Ms. Taylor's treaters likely changed their initial diagnosis of MS to ADEM because Ms. Taylor experienced a "single episode of neurological abnormalities." *Id.* at 5. But apart from noting that Ms. Taylor experienced diffuse demyelination and a white matter disease, Dr. Souayah's report did not include extensive consideration of the MRI evidence, nor did he mention the presence of oligoclonal bands (a factor favoring an MS diagnosis). *Id.* at 15, 21.

The remainder of Dr. Souayah's report discussed the biologic mechanisms known to cause ADEM, including molecular mimicry, as discussed in more detail by Dr. Steinman above. Consistent with Dr. Steinman, Dr. Souayah opined that there is support in the medical literature suggesting a flu/ADEM association by way of molecular mimicry. *See generally* Souayah Rep. at 16-19.

C. *Dr. Subramanian Sriram*

Respondent's first expert, Dr. Sriram, prepared two expert reports in total and testified at the hearing. *See* Sriram First Report, dated July 20, 2015, filed as Ex. A (ECF No. 35-1) ("Sriram Rep."); Sriram Second Report, dated May 4, 2016, filed as Ex. E (ECF No. 48-1) ("Sriram Second Rep."). He opined that it was more likely than not that the flu vaccination that Ms. Taylor received was unrelated to the neurologic deficits that she developed, and also proposed that her proper diagnosis was MS beginning before the vaccination in question.

Dr. Sriram obtained his bachelor's and medical degrees at the University of Madras in India, completing his residency in internal medicine at Wayne State University followed by a neurology residency and at Stanford University. Sriram CV, filed as Ex. B (ECF No. 35-2) at 1. He then went on to complete a four year neuroimmunology fellowship at Stanford, before becoming director of the MS Center at the University of Vermont for about 10 years. *Id.* Today, Dr. Sriram directs the MS Center at Vanderbilt Medical Center, where he sees patients while also serving as a Professor of Neurology and Experimental Therapeutics. Tr. at 70-71. Dr. Sriram sees approximately 35 patients per week, 80 percent of whom have MS, with the remainder having some other neurological disease. *Id*. Relying on his experience treating patients with autoimmune demyelinating disorders, Dr. Sriram formulated an opinion in this case after reviewing Petitioner's medical records, and pertinent medical or scientific literature. *Id.* at 76.

To begin, Dr. Sriram described the clinical metrics used to diagnose a patient with ADEM based on the International Pediatric MS Study Group criteria. He emphasized that ADEM is an acute inflammatory condition of the central nervous system, brain, and spinal cord. Tr. at 76-77. ADEM is a monophasic disorder, typically lasting no more than four to six weeks before the patient recovers. *Id.* at 77. It occurs most commonly with children, usually presenting with multiple abnormal areas on an MRI in the white matter of the brain ("large, enhancing multifocal lesions"), and with evidence of inflammation (as established by CSF testing revealing oligoclonal bands). *Id.* at 76-77, 81-82. In addition, ADEM usually includes a polysymptomatic onset of symptoms (including behavioral changes, confusion, excessive irritability, lethargy, or coma) - and in his view *must* include evidence of an encephalopathy. Sriram Rep. at 4.

Dr. Sriram briefly compared the diagnostic criteria for ADEM versus MS, relying on Krupp as well as additional scientific authority. Tr. at 78; Sriram First Rep. at 4; N. Young, et al., *Acute Disseminated Encephalomyelitis: Current Understanding and Controversies*, 28 Seminal

Neurology 84 (2007), filed as Ex. C (ECF No. 35-3). An ADEM patient's MRI would *rarely* indicate the presence of oligoclonal bands in the CSF, which are closely associated with MS (because they establish "containment of the inflammation within the central nervous system"). *Id.* at 82-83. MS, on the other hand, is a seemingly flu-like disease prevalent in young adults and adolescents, specifically females, and is normally *not* accompanied by encephalopathy. *Id.* at 79. In addition, unlike ADEM (which can include seizures), seizures rarely accompany MS. *Id.* at 80. While lesions can appear on an MRI of an MS patient, they are more common in adolescents than adults, and can mimic an ADEM-like, "aggressive-looking" picture. *Id.* at 81; Sriram First Rep. at 3.

Taking the above into consideration, Dr. Sriram contended that Ms. Taylor was improperly diagnosed with ADEM. Rather, in his opinion her diagnosis should have been aggressive MS or "relapsing-remitting MS," offering several factors to support his opinion. Tr. at 83, 90. First, Ms. Taylor's age (seventeen) at the time of diagnosis was more supportive of MS, given what is known about ADEM's association with younger children. *Id.* at 83. Second, Dr. Sriram noted that he saw no evidence of an encephalopathy at onset – a factor in his view critical to an ADEM diagnosis. *Id.* at 84, 89. Her CFS testing also revealed oligoclonal bands, a finding more consistent with an MS diagnosis. *Id.* at 83. Dr. Sriram additionally categorized Ms. Taylor's symptomology course as multi-event, rather than a single, discrete, acute event. *Id.* Finally, Ms. Taylor's initial MRI images revealed "multiple enhancing lesions," while the MRI she received five years later, in 2016, showed "no white matter . . . of any discernable image characteristics," indicating to him that her condition had progressively worsened instead of resolving, as would be expected with ADEM. *Id.* at 86-87.[11]

Dr. Sriram particularly emphasized a broader view of Ms. Taylor's overall treatment, observing that his preferred diagnosis was best supported if the records from 2010 to 2016 were considered *in toto*, rather than focusing merely on 2010-2011. Thus, he noted that in April 2011, Ms. Taylor presented to her neurologist with a normal gait. Tr. at 121. She presented also in June 2011 for her seizure disorder, but experienced no further worsening of neurological function until almost five years later, when an MRI in April 2016 indicated substantial demyelination and a new lesion on the left side of her brain. *Id.* at 121-22. Dr. Sriram opined that this course of symptomology, including new lesions, was suggestive of "very rapidly-progressing MS." *Id.* at 122, 124, 128. Ms. Taylor's 2016 MRI also revealed demyelinating lesions completely covering both brain hemispheres. *Id.* at 128. This type of progression over five years, Dr. Sriram opined, is typical for an MS patient who has not received proper treatment. *Id.* at 128, 130. Dr. Sriram added, however, that he was not surprised that Ms. Taylor's treaters originally diagnosed her with ADEM, based on the limited record before them. Tr. at 117; *see also* Sriram First Rep. at 6;

[11] Dr. Sriram allowed that Petitioner's presentation did satisfy some of the diagnostic criteria for ADEM. In particular, he acknowledged that Ms. Taylor's seizures could favor an ADEM diagnosis, but maintained that ADEM seizures are acute, and manifest *during* the ADEM event - not four to five months later, as in Ms. Taylor's case. Tr. at 84, 89.

Sriram Second Rep. at 1. He also allowed for the possibility that the varying diagnoses could be the product of differing of opinions between a resident and staff, or the treaters' lack of experience in treating MS patients. *Id.* at 115, 129.

Dr. Sriram devoted some time at hearing to addressing whether Petitioner had experienced an encephalopathy in the fall of 2010, and thus closer in time to her vaccination. To this end, he completed his own categorization of her health history and labeled certain events as encephalopathic or not. *See* Tr. at 94-113. Dr. Sriram dismissed Dr. Steinman's contention that Ms. Taylor had experienced an encephalopathic event in connection with her flag football injury in October 2010. *Id.* at 95, 98. Rather, Ms. Taylor's symptoms at this time were likely a result of her current medications, including the antihistamine Claritin. *Id.* at 98. Dr. Sriram further rejected Petitioner's assertion that she had experienced an encephalopathic event in November 2010, opining that the records from this treatment event suggested her symptoms were more attributable to anticholinergic and histaminic drugs than to a neurological condition. *Id.* at 99-101. Dr. Sriram also attempted to distinguish conduct from Ms. Taylor's February 2011 hospital visit (at which time she displayed "child-like" behavior) as not evidencing encephalopathy, arguing that it was attributable instead to a "pseudobulbar affect," or a "clear disconnection between the normal breaks that we use to control our emotions" that would not be associated with ADEM but rather with MS. *Id.* at 111, 113.

Besides disputing the proper diagnosis, Dr. Sriram proposed that Petitioner's neurologic symptoms actually began *pre-vaccination*, on March 4, 2010, when she presented to her ophthalmologist with cranial nerve palsy, headaches, and right eye pain. Tr. at 91, 94; Sriram Second Rep. at 1. Dr. Sriram disagreed with Dr. Steinman's categorization of this record as maybe "an attack of MS," but more likely "due to migraine." *Id.* at 93. While Dr. Sriram acknowledged that MS patients can experience migraines, he contended that ophthalmoplegic migraines are extremely rare. *Id.* He instead interpreted these symptoms to reflect a brainstem event that caused her to have cranial nerve abnormalities, consistent with MS. *Id.* at 94. Otherwise, Ms. Taylor's first clinical manifestation of neurological symptoms following vaccination occurred no earlier than December 2010 (sixty-five days after vaccination), with complaints of numbness in her foot. Tr. at 103; Sriram First Rep. at 5.

Dr. Sriram characterized the overall progression of Ms. Taylor's clinical course (from her initial diplopia in March 2010, to the foot numbness in December 2010 (nine months later), the hospitalization in February 2011, and on to 2016) as consistent with MS patients he has treated. Tr. at 214. According to Dr. Sriram, Petitioner experienced two relapses after her March 2010 doctor's visit, revealing an autoimmune, acute inflammatory change of the brain common in MS. *Id.* As Dr. Sriram opined, the body generally can resolve some inflammation on its own, eliminating brain lesions with or without some residual deficit, and thereby causing an up and down course of symptoms. *Id.* at 214, 217. He has treated patients who have experienced a relapse

almost eleven months later. *Id.* Ms. Taylor's overall five-year course of symptoms was consistent with his experience. *Id.* at 218-19.

In addressing onset issues, Dr. Sriram proposed that (relying on Dr. Steinman's citation to animal model research involving EAE[12]), ADEM's onset (after infection or vaccination) would be highly unlikely to occur in a period longer than twenty-five days post-vaccination. Tr. at 162, 222. For MS, by contrast, Dr. Sriram allowed that a relapse could occur at any time. *Id.* at 223. However, he dismissed out of hand the possibility that (assuming her MS began pre-vaccination) Ms. Taylor's MS could have been significantly aggravated by her September 2010 vaccination. *Id.* at 222.

In so reasoning, Dr. Sriram maintained that no clinical or epidemiological evidence exists standing for the proposition that the flu vaccine can cause an MS relapse. Tr. at 131; Sriram Second Rep. at 2. In support, he referenced two retrospective studies suggesting that vaccinations were unlikely to cause MS relapse (let alone MS in the first place). *Id.* at 132; C. Confavreux, et al., *Vaccinations and the Risk of Relapse in Multiple Sclerosis*, 344 New Eng. J. Med. 319 (2001), filed as Ex. I (ECF No. 76-3) (study of 643 patients in Europe, 15 percent of whom were vaccinated prior to MS relapse, and concluding that vaccination does not increase short-term risk of MS relapse); M. Loebermann, et al., *Vaccination Against Infection in Patients with Multiple Sclerosis*, 8 Nat. Rev. Neuro. 143 (2001), filed as Ex. J (ECF No. 76-4) (study concluding that inactive vaccines, such as the flu vaccine, are considered safe for MS patients, although live virus vaccines might initiate a relapse). He added that the concept of vaccine-induced MS relapse was not supported by clinical practice guidelines or immunological evidence relating to relapsing patients. Sriram Second Rep. at 2.

D. *Dr. James Lindsay Whitton*

Respondent's second expert, Dr. Whitton, submitted one written report and testified at hearing, proposing that the flu vaccine has not herein been shown to either cause ADEM or MS, or to significantly aggravate either illness. *See* Whitton Expert Report, dated Sept. 19, 2016, filed as Ex. F (ECF No. 58) ("Whitton Rep.").

Dr. Whitton is currently a professor in the Department of Immunology and Microbial Science at the Scripps Institute in La Jolla, California, and has served in this capacity since 1998. Tr. at 226. He received his medical degree from the University of Glasgow in Scotland. Tr. at 228; Whitton CV, filed as Ex. N (ECF No. 77-4) at 1. He also received a Ph.D. in molecular biology from the University of Glasgow. Whitton CV at 1. His practice consists almost

[12] Experimental allergic encephalomyelitis or "EAE" refers to a series of animal model studies aimed at understanding the causal connection between neurological damage and viral infections. *See* L. Steinman et al., *How to Successfully Apply Animal Studies in Experimental Allergic Encephalomyelitis to Research on Multiple Sclerosis*, 60 Ann. Neurol. 12, 12-13 (2006), filed as Ex. 19 (ECF No. 71-2).

exclusively of research related to viral immunology, although he also oversees a graduate student program focused on virology and immunology. Tr. at 227. Eighty to ninety percent of his research involves immune system responses to viruses, bacteria, and live virus vaccines. *Id.* at 231. He has also served on the editorial board of various academic journals focused on virology. *Id.* at 227. Dr. Whitton currently serves as an editor of *Virology* and has published roughly 35 papers on DNA vaccines. *Id.* at 231. Dr. Whitton does not see patients and is not currently licensed to practice medicine in the United States. *Id.* at 233.

Dr. Whitton maintained that the flu vaccine administered to Ms. Taylor - specifically Fluvirin[13] - could not cause MS or ADEM.[14] Tr. at 235. In so opining, he dismissed *all* molecular mimicry theories offered by Dr. Steinman as unreliable evidence of causation. First, he took issue with Dr. Steinman's opinion that there was sufficient homology between components of the flu vaccine and MBP for an autoimmune cross-reaction via molecular mimicry to occur. *Id.* at 237. The medical literature presented by Dr. Steinman in support established sequence homology only with respect to the Influenza A virus - not to flu virus components in Fluvirin. *Id.*; Whitton Rep. at 2. Thus, according to Dr. Whitton, the alleged sequence homology proposed by Dr. Steinman (HFFK or FFKN)[15] was not present in Fluvirin, the vaccine Ms. Taylor received. *Id.* at 240, 265; Whitton Rep. at 9. Dr. Whitton further maintained that sufficient sequence homology (between five and twelve shared amino acid peptides) is needed between the virus protein and the vaccine to warrant a possible reaction, and therefore was not possible with such a short amino acid sequence. *Id.* at 280.

Dr. Whitton next characterized Markovic-Plese as inadequate support for Dr. Steinman's theory that a cross-reaction between MOG and CNPase proteins in the CNS was plausible. According to Dr. Whitton, the homology sequence presented by Dr. Steinman is not present in the MOG or CNPase protein. Tr. at 259, 275; Whitton Rep. at 2-3. He also critiqued Markovic-Plese for not using a control, noting that its authors did not compare the reaction of healthy T-cells to MOG or CNPase proteins. *Id.* at 276. Furthermore, he noted that the paper involved an MS patient with an acute, live virus infection - not a vaccinated patient. *Id.* at 252. Dr. Whitton

[13] Fluvirin is a trivalent, sub-unit influenza virus vaccine containing 45 mcg hemagglutinin (HA) per .5mL dose in the recommended ratio of 15mcg HA of each of the following three viruses: A/California/07/2009, A/Perth/16/2009, and B/Brisbane/60/2008. *See Fluvirin Package Insert*, FDA, https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm112852.htm (last accessed on Feb. 26, 2018); *WHO Influenza Strains*, Influenza Research Database, https://www.fludb.org/brc/vaccineRecommend.spg?decorator=influenza#2010-2011_Northern Hemisphere (last accessed on Feb. 26, 2018).

[14] Dr. Whitton stated that his comments apply generally to both MS and ADEM, and he did not offer an opinion as to the proper diagnosis for Ms. Taylor's symptoms. Tr. at 235.

[15] Dr. Whitton analyzed the relevant protein sequences in the three vaccine viruses contained in the 2010-2011 Fluvirin vaccine and found the following sequences in two strains: EKDMTKE**FFEN**SETW and EKDMTKE**FFEN**SEAW. Whitton Rep. at 9. Thus, his research confirmed his conclusion that sequence homology was not present in Fluvirin. *See id.*

also found the paper to be unpersuasive because it showed no indication that the MS patient discussed had suffered from an MS flare following vaccination, suggesting that the T-cells involved were not neuropathic in nature. *Id.* at 253-54. Evidence of a T-cell specific reaction with the MOG or CNPase proteins, resulting in an MS relapse, would have been a significant finding, and thus would have been highlighted by the Markovic-Plese authors. *Id.* at 255.

Finally, Dr. Whitton dismissed the element of Dr. Steinman's theory proposing that ganglioside molecules in the CNS were the target of an autoimmune attack. In Dr. Whitton's view the current literature on the topic suggests that ADEM and MS are both T-cell driven diseases – suggesting in turn that B cell-driven antibody production is *not* implicated in the pathologic process resulting in either disease. Tr. at 256; Whitton Rep. at 5. Accordingly, an autoantibody attack against such gangliosides had not been shown to be relevant to the pathogenesis of these diseases (unlike in GBS). *Id.* at 257; Whitton Rep. at 6. Dr. Whitton specifically dismissed the Nachamkin paper cited by Dr. Steinman in support of his ganglioside theory. Whitton Rep. at 6-7. Nachamkin specifically states that its results *did not* support anti-ganglioside antibody induction in either a human subject or a vaccinated mouse. *Id.* Furthermore, Dr. Whitton noted that the paper does not mention or apply to ADEM/MS, but only discusses GBS in the swine flu context. *Id.* at 6-7.

IV. Procedural History

Ms. Taylor filed her Petition on September 19, 2013. Pet. at 1. Almost six months later, after some records in the case had been filed, on April 28, 2014, Respondent filed his Rule 4(c) report denying that Ms. Taylor was entitled to compensation. ECF No. 20. The Statement of Completion was then filed on September 15, 2014. ECF No. 29.

Thereafter, the parties began filing expert reports. Petitioner filed an initial expert report from Dr. Souyah on April 10, 2015. ECF No. 33. Respondent filed an initial expert report from Dr. Sriram on July 20, 2014. ECF No. 35. Following a status conference in August 2015, Petitioner filed a supplemental report from Dr. Steinman on December 15, 2016, and Respondent filed a supplemental report on May 4, 2016. ECF No. 48. Thereafter, in August of 2015, I scheduled a hearing for May 25-26, 2017, to determine entitlement. ECF No. 54. Prior to the hearing, Respondent filed an additional supplemental report by Dr. Whitton on September 19, 2016. ECF No. 58.

The entitlement hearing was held in piecemeal fashion, to accommodate expert schedules, with one day of hearing occurring in April and then the final two days occurring in May 2017. That hearing included testimony from the experts identified above (with the exception of Dr. Souayah). Following the hearing's conclusion, the parties submitted post-hearing briefs on September 29, 2017. ECF Nos. 87-86. The matter is ripe for adjudication.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that she suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that her illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[16] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the

[16] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish her overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[17]

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be

[17] There is ample contrary authority for the more straightforward proposition that the first *Althen* prong, like the overall test itself, simply applies a preponderance standard when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010). For purposes of the present analysis, I am stressing those cases focusing on the *plausibility* of the causal theory proposed, as opposed to whether preponderant evidence supports it, in order to avoid imposing on Petitioners a greater evidentiary burden than the law requires. This does not, however, change the fact that *any* theory's plausibility, for purposes of satisfying the *Althen* test, is properly analyzed by subjecting its components to the *Daubert* tests for scientific reliability. *Terran v. Sec'y of Health & Human Servs*., 195 F.3d 1302, 1316 (Fed. Cir. 1999).

considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dep't of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is

within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (*i.e*., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd, Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneously medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19

("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion

"connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339).

Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act"). It is in the exercise of my duties as a special master to weigh competing expert testimony. *Copenhaver v. Sec'y of Health & Human Servs.*, 129 Fed. Cl. 176, 183 (2016) ("Special Masters may use their discretion in weighing expert testimony, and case law supports that discretion").

In determining whether a particular expert's testimony was reliable or credible, I may consider whether the expert offers an opinion that exceeds his training or competence. *Walton v. Sec'y of Health & Human Servs.*, No. 04-503V, 2007 WL 1467307, at *17-18 (Fed. Cl. Spec. Mstr. Apr. 30, 2007) (otolaryngologist not well suited to testify about disciplines other than her own specialty). While (in keeping with the liberality with which evidence offered in Vaccine Program cases is treated) I heard and have considered all of the testimony of the experts offered at the entitlement hearing, I may properly evaluate, and give appropriate weight to, whether certain testimony is beyond a particular expert's purview. *See, e.g., King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296, at *78-79 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (petitioner's expert far less qualified to offer opinion on general causation issues pertaining to autism than specific issues pertaining to the petitioner's actual medical history, given the nature of the expert's qualifications).

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, including some articles (such as those discussing molecular mimicry and protein sequences in vaccines) that do not factor into the outcome of this decision. I have reviewed all of the medical literature submitted in this case, but I only discuss those articles that are most relevant to my determination and/or are central to Petitioners' case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record

evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to — and likely undermines — the conclusion that it was not considered").

ANALYSIS

I. ADEM and MS

As I have noted in other cases, ADEM is an inflammatory demyelinating disease of the central nervous system characterized by an acute onset and a monophasic course. *See Caruso v. Sec'y of Health & Human Servs*., No. 15-200V, 2017 WL 5381154, at *12-13 (Fed. Cl. Spec. Mstr. Oct. 18, 2017), *appeal docketed*, No. 15-200V (Fed. Cl. Nov. 17, 2017); *Bell v. Sec'y of Health & Human Servs*., No. 13-709V, 2016 WL 8136297, at *24 (Fed. Cl. Spec. Mstr. Dec. 1, 2016). ADEM features an autoimmune attack on the myelin sheath of the central nervous system that leads to inflammation and swelling in the brain and spinal cord.[18] When the myelin is damaged, nerve impulses can slow or stop, causing a range of neurological problems.[19] Symptoms can include fever, headache, vomiting, tremors, seizures, and paralysis.[20] ADEM is more common in children or young adults.

An important feature distinguishing ADEM from MS is its abrupt onset, as it will usually occur within a few days to a month of the instigating insult. *See Caruso*, 2017 WL 5381154, at *12-13. Upon MRI testing, lesions are found in the brain of patients suffering from ADEM, but these lesions later resolve, consistent with the monophasic nature of the disease. *Id*. A patient may in rare circumstances experience a relapse of ADEM symptoms, but such patients have usually already experienced an abrupt initial onset, and the later symptoms are not accompanied by new or worsened lesions. *Id*.

MS can also be categorized as a demyelinating central nervous system disease. However, it is more typical in adolescent females. *See* L. Krupp, et al., *Consensus Definitions Proposed for Pediatric Multiple Sclerosis and Related Disorder*s, 68 Neurology S7 (2007), filed as Ex. D (ECF No. 35-4) ("Krupp"). Patients with MS typically experience multiple episodes of CNS demyelination "separated in time and space[,]" evidencing a more progressive decline in their overall health course, unlike ADEM. Krupp at S11. An MRI can be used to corroborate the "dissemination" in space and time requirement, and often reveals old lesions as well as enhancing

[18] Dorland's Illustrated Medical Dictionary 613 (32nd ed. 2012) [hereinafter *Dorland's*]; *ADEM Overview*, Nat'l MS Soc'y, http://www.nationalmssociety.org/What-is-MS/Related-Conditions/Acute-Disseminated-Encephalomyelitis-(ADEM) (lasted visited on Feb. 26, 2018).

[19] *Demyelinating Disease: What Can You Do About It?*, Mayo Clinic (2017), http://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/expert-answers/demyelinating-disease/faq-20058521 (last visited on Feb. 26, 2018).

[20] *Dorland's* at 613.

or new lesions. *Id.* Furthermore, evidence of oligoclonal bands in CSF testing, which reveal brain inflammation, is frequently seen in patients with MS, but less commonly associated with an ADEM diagnosis. *Id.* at S8. General symptoms can include numbness or weakness in body, loss of vision, tremors, unsteady gait, slurred speech, fatigue, and dizziness.[21]

II. Onset of Ms. Taylor's Neurologic Symptoms Likely Occurred in December 2010

While the parties dispute Petitioner's proper diagnosis, they agree generally that the various neurologic symptoms (and/or symptoms that could be interpreted as neurologic) Ms. Taylor experienced could support *either* an ADEM or MS diagnosis. They also agree that the *diagnosis* of Ms. Taylor's illness would reasonably lag after onset of symptoms, and therefore the timing of that diagnosis does not shed substantial light on when she first experienced symptoms relevant to it. Accordingly, determining an onset of the symptoms themselves, whether attributable to ADEM or MS, is necessary.

Petitioner and her experts argue for an onset of about two weeks after the September 2010 vaccination, pointing to the records of Ms. Taylor's treatment after her flag football injury (as supplemented by fact witness testimony). Petitioner maintains that at this time she felt weak, tired, and had some mental recollection problems arguably characterizing an encephalopathy, and also point to an alleged unsteady gait that precipitated the injury. *See, e.g.*, Ex. 12 at 2. The records from this doctor's visit, however, are devoid any evidence of, or complaints about, neurologic deficits at the time. Ex. 1 at 4. Moreover, the subsequent records from the fall of 2010 do not corroborate this as the beginning of a neurologic decline. Indeed – the February MRI strongly supports the conclusion that Petitioner's brain lesions (which were deemed "enhancing" at the time, and hence new) had begun not long before – not four months earlier. And as Dr. Steinman acknowledged, some of Ms. Taylor's medical complaints in the period before her February 2011 diagnosis were as likely as not unrelated to her established neurologic problems, making it even more difficult to draw a line from October to February. Tr. at 21-22. I thus do not find persuasive arguments placing onset of Petitioner's neurologic symptoms in October 2010.

Respondent argues contrarily for an onset beginning *before* vaccination, evidenced by Petitioner's doctor's visit in March 2010. But this reading of the record is also unpersuasive. Certainly the vision problems that Petitioner was experiencing at that time *could* have been presenting evidence of a deeper neurologic condition – but nothing in the record for the ensuing five to six months corroborates that supposition, any more than the overall record from October 2010 to February 2011 suggests progression of neurologic symptoms. Respondent's argument also assumes an MS diagnosis was appropriate – but (as discussed below) that contention is far more persuasively supported by records from long after this period of time (and after the initial

[21] *See Multiple Sclerosis*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/symptoms-causes/syc-20350269 (last accessed on Feb. 27, 2018).

ADEM diagnosis – which itself was the result of what treaters saw before them, as well as the testing results they obtained at that time).

Taking all of the above into account, I find the record best supports the conclusion that Ms. Taylor's neurologic symptoms relevant to her claim herein began no earlier than December 2010. The testifying diagnostic experts deemed this treatment incident significant, and it was the first instance in which Petitioner clearly in a record complained of something (foot numbness) that suggested the start of the neurologic problems resulting in her hospitalization. Her medical visits earlier that fall do not as forcefully display any signs of neurologic problems or complaints, by contrast. This December instance is also temporally close to the time in the winter of 2011 when Petitioner's symptoms became sufficiently severe to impel her to seek emergency care (at which time MRI and other testing was performed that could substantiate the initial ADEM diagnosis). The records from the February 2011 visit actually suggest Petitioner reported at the time that her symptoms began only *the month before*, or January 2011, further diminishing the likelihood that her symptoms began as early as Petitioner argues.

III. The Onset of Ms. Taylor's Symptoms did not Occur in a Medically Acceptable Timeframe (*Althen* Prong Three)

Approximately eleven weeks passed from the date Petitioner received the flu vaccine in late September to when she experienced what the record suggests was her first neurologic symptom in late December (intermittent numbness in her left foot that she feared reflected a diabetic neuropathy). Assuming that Petitioner was thereafter properly diagnosed with ADEM (as Petitioner argues), the timeframe from vaccination to onset is entirely too long.

ADEM is understood to be an acute condition with an onset occurring in a few weeks – not months. *Stillwell v. Sec'y of Health & Human Servs.,* No. 11-77V, 2013 WL 4540013, at *16 (Fed. Cl. Spec. Mstr. June 17, 2013), *mot. for review den'd,* 118 Fed. Cl. 47 (2014); *see also Caruso*, 2017 WL 5381154, at *16 (denying entitlement where ADEM symptoms began two months post flu vaccination); *Rich v. Sec'y of Health & Human Servs*., No. 12-742V, 2016 WL 3996334, at *8 (Fed. Cl. Spec. Mstr. June 30, 2016), *mot. for review den'd*, 129 Fed. Cl. 642 (2016) (denying entitlement where ADEM symptoms occurred three months post flu vaccination). Even Petitioner's experts, like Dr. Steinman, admitted reluctance to opine that a timeframe in which onset did *not* occur in October or November 2010 was medically acceptable. Tr. at 41, 43.

Ms. Taylor's medical history leading to her February 2011 hospitalization also factors into my analysis. To find for Petitioner in this case, I would have to accept that vaccine-induced ADEM could take almost three months to "set up" an autoimmune reaction sufficient to manifest outward neurologic injury, but then take *another* four to six weeks to become severe enough to require hospitalization. This course of illness, clearly established by the record in this case, is not

consistent with ADEM's course as best understood. *See* Tr. at 83-90; Sriram First Rep. at 3-4**.** Accordingly, Petitioner's claim founders on the third *Althen* prong.

In reaction to Respondent's argument that Petitioner actually suffered from MS which began before vaccination, Petitioner has also proposed that the vaccine could have exacerbated that MS, and that such MS relapses (such as her December 2010 foot numbness) could have occurred in a medically acceptable timeframe. However, because I do not find that the record supports the conclusion that Ms. Taylor's neurologic condition (however it was characterized) *did* predate the vaccination, this alternative causation theory is mooted and is not further discussed.[22]

IV. Remaining *Althen* Prongs

Because this claim can be resolved based on one of the *Althen* prongs, substantial additional discussion of the remaining two prongs is unnecessary. *See, e.g., Lasnetski v. Sec'y of Health & Human Servs.*, 128 Fed. Cl. 242, 264 (2016), *aff'd*, 696 F. App'x 497 (Fed. Cir. 2017) (not error for special master to forego *Althen* analysis after determining that a petitioner had not in fact experienced the disease or illness alleged to have been vaccine-caused). I will, however, briefly note the following points relevant to the complete analysis.

Petitioner's showing on the "can cause," first prong -- that the flu vaccine can cause ADEM -- has both scientific reasonableness and plausibility, and was effectively supported by the literature filed as well as expert testimony offered. Dr. Steinman's expertise with central nervous system disorders and the field of immunology renders him well qualified to opine on the causal potential of vaccines in producing ADEM or MS. There are also numerous instances in the Vaccine Program in which other special masters (including me) have determined that a petitioner successfully established a plausible causation theory involving the capacity of different vaccines, including the flu vaccine, to cause ADEM or similar central nervous system neurologic injuries. *See, e.g., Caruso v. Sec'y of Health & Human Servs.,* No. 15-200V, 2017 WL 5381154, at *14 (Fed. Cl. Spec. Mstr. Oct. 18, 2017) (flu vaccine); *Lozano v. Sec'y of Health & Human Servs.*, No.

[22] An alternative conclusion, consistent with Dr. Sriram's interpretation of Petitioner's 2016 MRI, is that Petitioner may have suffered from MS that began *after* the vaccination. Of course, neither side proposed this reading of the record, nor did Petitioner's treaters propose that the proper diagnosis for her *was* MS, so it need not be given substantial consideration. However, even if Petitioner had so alleged, I would still find that the overall timeframe (from the September 2010 vaccination, to initial onset in December 2010, and then to the February worsened symptoms that resulted in her hospitalization and the discovery of the brain lesions – a total period of five months) is too long to be medically appropriate. Other special masters have found that the medically appropriate timeframe for onset of MS symptoms after receipt of vaccination is no longer than two months. *See, e.g., Lippa v. Sec'y of Health & Human Servs.*, No. 99-202V, 2010 WL 3743870, at *2 (Fed. Cl. Spec. Mstr. Aug. 30, 2010) (dismissing case where MS symptom onset occurred four months post Hep B vaccination); *Fisher v. Sec'y of Health & Human Servs.*, No. 99-432V, 2009 WL 2365459, at *3, 20 (Fed. Cl. Spec. Mstr. July 13, 2009) (two month timeframe is medically acceptable for onset of MS symptoms following Hep B vaccine); *Doe/29 v. Sec'y of Health & Human Servs.*, 2009 WL 180078, at *1, 4 (Fed. Cl. Spec. Mstr. Jan. 21, 2009) (same).

15-369V, 2017 WL 3811124, at *13 (Fed. Cl. Spec. Mstr. Aug. 4, 2017) (finding for entitlement where onset of ADEM occurred 21 days post-Tdap vaccination).

At the same time, Respondent identified weaknesses in the causation theory that are intriguing. In particular, Dr. Whitton offered compelling testimony that called into question the possibility that the flu vaccine's components could actually result in an autoimmune cross-reaction producing central nervous system demyelination associated with MS or ADEM, and also pointed out the lack of reliable scientific evidence in the theory identifying the likely target for this CNS attack. Because the case decisively turns on onset and timing, I need not decide conclusively if Petitioner carried her burden on this component of the *Althen* test – although to the extent the evidence presented on this aspect of Petitioner's burden was close, I would necessarily have to decide it in Ms. Taylor's favor. *See Althen*, 418 F.3d at 1280; *Boatmon v. Sec'y of Health & Human Servs.*, No. 13-611V, 2017 WL 3432329, at *3 (Fed. Cl. Spec. Mstr. July 10, 2017).[23]

With regard to the second, "did cause," *Althen* element, however, two significant problems arise in the proof that lead me to state more unequivocally that Petitioner has not met this part of her evidentiary burden. First, the record is somewhat inconsistent as to *what* Petitioner's injury actually was. It is indisputable that Ms. Taylor's treaters initially proposed ADEM as the proper diagnosis (although they also considered MS in the differential, and the reasoning behind their determination to limit the diagnosis to ADEM is not fully explicated in the filed records). Ex. 2 at 303. As noted above, however, a treater's opinion need not be accepted wholesale. *Snyder*, 88 Fed. Cl. at 746 n.67. Rather, I may evaluate a treater opinion in light of the overall evidence, and conduct an analysis that properly conforms to the preponderant evidentiary test governing Vaccine Program claims.

The February 2011 MRI results, which suggest only new lesions, are particularly credible evidence supporting the ADEM diagnosis. Yet, as Dr. Sriram persuasively pointed out, even at the time of Ms. Taylor's initial presentation there was evidence somewhat undercutting that diagnosis, such as the presence of oligoclonal bands in her CSF testing, or lack of strong evidence of an encephalopathy. Further doubt is cast on the accuracy of the ADEM diagnosis when the scope of analysis is broadened to include Ms. Taylor's history in ensuing five years. The 2016 MRI in particular corroborates Dr. Sriram's views that Petitioner's illness may not simply have been ADEM after all (and that an initial misdiagnosis led to incomplete care). Ex. 40 at 4214, 4217.

Petitioner's early disease progression also seemed consistent with ADEM as well – and in particular the success of her treatment at the time. But, rather than proceeding in an acute and monophasic pattern, as would be expected for ADEM, Ms. Taylor continued to display a slower progression in a variety of neurologic symptoms over the next few months, with treaters assuming ADEM was no longer part of Petitioner's diagnostic picture. Thus, during Petitioner's June 2011

[23] I also note, however, that in a case in which other factors were more legitimately disputed – in particular, if onset had credibly occurred in a timeframe that was medically acceptable – I would likely scrutinize in greater detail Petitioner's first prong showing, given the legitimate points raised by Dr. Whitton.

hospital visit (for complaints of loss of consciousness, vision problems and seizures), ADEM was noted in Ms. Taylor's health history, but treaters did not opine if the seizures she was experiencing were related to her ADEM, noting upon discharge that her diagnoses included a seizure disorder and hypertension. Ex. 8 at 2343.

Given the above, it is difficult to conclude firmly that in fact Petitioner did suffer from ADEM despite her initial diagnosis. However, there is enough record support for it to make this a close case – which means there is just enough evidence to conclude that it preponderates in favor of ADEM as the diagnosis.

But this leads to the second problem with Petitioner's *Althen* prong two showing – and it is not a close call. This is because Petitioner's causation theory remains substantially undercut by the lack of record support favoring her allegations that the flu vaccine *caused* her ADEM. In addition to an absence of persuasive evidence of neurologic injury before December 2010, the record is devoid of evidence suggesting that in the period from the end of September until the end of the year, Petitioner was experiencing an underlying autoimmune process that would later manifest as ADEM or something like it. There is nothing, for example, that could indirectly corroborate the allegation that she was experiencing damaging inflammation on a chronic level – and certainly no direct proof either measuring such inflammation before February 2011. All that is left is the fact that Petitioner's diagnosis post-dated her vaccination – and that is not compelling, preponderant proof of a "logical sequence of cause and effect" sufficient to obtain an entitlement award.

CONCLUSION

Ms. Taylor has unquestionably suffered a life-altering injury, whatever its cause, and the fact testimony at the hearing credibly established the suffering she and her family have experienced in its aftermath. But the Vaccine Act permits me to award compensation only if a Petitioner alleging a "non-Table Injury" can show by medical records or competent medical opinion that the injury was more likely than not vaccine-caused. Here, Petitioner's causation theory is not supported by Petitioner's actual experiences, given the timeframe in which her neurologic symptoms began as well as the overall manner in which they unfolded. It is difficult to deny compensation to an individual who is demonstrably ill – but that difficulty does not mean Petitioner carried her burden of proof.

I therefore **DENY** this claim. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master